



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0665]

#### George Kuiper: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring George Kuiper for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Kuiper was convicted of multiple felony offenses: one count of smuggling, one count of conspiracy to smuggle goods into the United States and to introduce into interstate commerce unapproved drugs, and one count of introduction into interstate commerce of unapproved drugs. The factual basis supporting Mr. Kuiper's convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Kuiper was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of December 8, 2021 (30 days after receipt of the notice), Mr. Kuiper had not responded. Mr. Kuiper's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On May 26, 2021, Mr. Kuiper was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the District of New Hampshire, when the court entered judgment against him for one count of smuggling in violation of 18 U.S.C. 545; one count of conspiracy to smuggle goods into the United States and to introduce into interstate commerce unapproved drugs in violation of 18 U.S.C. 371 and 545 and sections 301(d) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(d) and 333(a)(2)); and one count of introduction into interstate commerce of unapproved drugs in violation of sections 301(d) and 303(a)(2) of the FD&C Act. FDA's finding that debarment is appropriate is based on the felony convictions referenced herein.

The factual basis for these convictions is as follows: as contained in the plea agreement in Mr. Kuiper's case, filed on December 21, 2020, from as early as 2006, and until June 2020, Mr. Kuiper operated an internet pharmacy through several websites which changed over the years. Specifically, Mr. Kuiper operated the website [nubrain.com](http://nubrain.com) until February 2015, when the registration for the website was revoked after FDA notified the domain name registrar that the website was selling products in violation of section 301 of the FD&C Act). Mr. Kuiper then immediately re-established his operations on a new website, [healthclown.com](http://healthclown.com). On both these

websites, Mr. Kuiper offered for sale over 100 types of products, including prescription drugs and controlled substances.

Mr. Kuiper's best-selling product through these websites was modafinil, a new prescription drug, and a Schedule IV controlled substance. FDA-approved modafinil, sold under the trade name PROVIGIL, is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, and it is only available by prescription. The version of modafinil Mr. Kuiper sold was not approved by the FDA, and it is therefore an unapproved new drug. FDA's Office of Criminal Investigations (OCI) conducted a number of controlled buys of unapproved modafinil and other unapproved prescription drugs from Mr. Kuiper's websites over approximately 11 years. On most occasions, the drugs were either received by OCI directly from shippers in foreign countries or had packaging indicating that they were manufactured in foreign countries. During subsequent interviews, Mr. Kuiper admitted to investigators that he caused unapproved modafinil to be shipped directly to customers from his overseas suppliers. OCI's purchases from Mr. Kuiper's websites never required a prescription.

As a result of his convictions, FDA sent Mr. Kuiper, by certified mail on October 28, 2021, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Kuiper's convictions for three felony counts under Federal law, specifically for one count of smuggling, one count of conspiracy to smuggle goods into the United States and to introduce into interstate commerce unapproved drugs, and one count of introduction into interstate commerce of unapproved drugs, were for conduct relating to the importation into the United States of any drug or controlled substance, because he knowingly conspired to illegally smuggle modafinil, an unapproved drug and controlled substance, into the United States on multiple occasions and then caused it to be introduced into interstate commerce.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Kuiper's offenses and concluded

that each felony offense warranted the imposition of a 5-year period of debarment. However, FDA placed significant weight on the cooperation Mr. Kuiper provided to law enforcement. Specifically, upon the execution of a search warrant by FDA's OCI, Mr. Kuiper immediately began to cooperate meaningfully with Federal agents and ceased his own operations.

In light of Mr. Kuiper's assistance, FDA determined that the 5-year debarment periods for each conviction should run concurrently. The proposal informed Mr. Kuiper of the proposed debarment, offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kuiper received the proposal and notice of opportunity for a hearing on November 8, 2021. Mr. Kuiper failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. George Kuiper has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Kuiper is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Kuiper is a prohibited act.

Any application by Mr. Kuiper for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0665 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 25, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-04484 Filed: 3/2/2022 8:45 am; Publication Date: 3/3/2022]